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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/729,118	12/04/2000	James Norman Cawse	RD-27,953	6825

7590 12/10/2002

General Electric Company
CRD Patent Docket Rm 4A59
P.O. Box 8, Bldg. K-1 - Salamone
Schenectady, NY 12301

EXAMINER

EPPERSON, JON D

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 12/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary <i>File Copy</i>	Application No.	Applicant(s)
	09/729,118 Examiner Jon D Epperson	CAWSE, JAMES NORMAN Art Unit 1639
-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --		
Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.		
<ul style="list-style-type: none"> Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 		
Status		
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>23 September 2002</u> . 2a) <input checked="" type="checkbox"/> This action is FINAL. 2b) <input type="checkbox"/> This action is non-final. 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4) <input checked="" type="checkbox"/> Claim(s) <u>1-7, 10-12 and 16</u> is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) <input type="checkbox"/> Claim(s) _____ is/are allowed. 6) <input checked="" type="checkbox"/> Claim(s) <u>1-7, 10-12 and 16</u> is/are rejected. 7) <input type="checkbox"/> Claim(s) _____ is/are objected to. 8) <input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.		
Application Papers		
9) <input type="checkbox"/> The specification is objected to by the Examiner. 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.		
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.		
14) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.		
15) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
Attachment(s)		
1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____		

DETAILED ACTION

Please note: The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1639.

Status of the Application

1. The Amendment filed September 23, 2002 (Paper No. 9) is acknowledged.

Status of the Claims

2. Claims 1-7 and 10-12 were amended and claims 8-9 and 13-15 were cancelled without prejudice (see Paper No. 9). Therefore, claims 1-7, 10-12 and 16 are pending (claims 17-36 were withdrawn as being directed to a non-elected invention).

Election/Restriction

3. This application contains claims 17-36 drawn to inventions nonelected. This was addressed in the previous action (see Paper No. 6, paragraph 3). A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Withdrawn Objections/Rejections

4. The objections to claims 14 and 15 are withdrawn in view of applicant's cancellation of said claims. With respect to the rejections under the second paragraph of 35 U.S.C. 112, the rejections denoted E-F and H-I are withdrawn in view of applicant's amendments to the claims and/or cancellation of claims. The rejection under the 35 U.S.C. 102(b) and 102(e) are withdrawn in view of applicants amendments. All other rejections are maintained and the arguments are addressed below.

Maintained Rejections

Maintained Claim Rejections -35 USC § 112, first paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 10-11 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an apparatus comprising a polycarbonate substrate and a permeable polycarbonate film covering used for the catalytic production of aromatic carbonates, does not reasonably provide enablement for *any* apparatus comprising *any* substrate and *any* permeable film covering used for *any* chemical reaction. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

It is clear from applicant's specification how one might produce the claimed invention only when the solid support and permeable film covering are composed of polycarbonate; however, there is insufficient guidance as to how to carry out the production of any apparatus comprising *any* substrate and *any* permeable film covering. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

- (1) the breadth of the claims;
- (2) the nature of the invention;
- (3) the state of the prior art;
- (4) the level of one of ordinary skill;
- (5) the level of predictability in the art;
- (6) the amount of direction provided by the inventor;
- (7) the existence of working examples; and
- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1-2) The breadth of the claims and the nature of the invention:

For claims 1-4, 10-11, 13-14 and 16, applicant has disclosed an apparatus that is very broad in scope. The "substrate" and "permeable film cover" can be composed of *any* material (e.g., polyester, glass, diamond), which reads on a limitless number of possibilities. Furthermore, the chemical and/or physical properties of the substrate and permeable film cover including the thickness have not been specified, which reads on a limitless number of physical possibilities.

For claims 5-7, the thickness of the permeable film was specified, but the composition of the permeable film was not (e.g., polyester, polycarbonate, etc.) and, as a

result, these claims are also very broad in scope because these claims read on all materials.

For **claims 8-9 and 15**, the composition of the permeable film was specified, but the thickness of the permeable film was not, and, as a result, these claims are also very broad in scope because these claims read on a limitless number of physical and chemical variations.

(3 and 5) The state of the prior art and the level of predictability in the art:

Only a few examples exist for “reactor plates” that comprise a “substrate” with an array of reaction cells” and a “permeable film covering” describing only a few different types of substrates with a few different types of permeable film coverings (see below, paragraphs 14 and 15 e.g., 102a and 102e rejections).

Furthermore, one of ordinary skill in the art could not predict which films (e.g., polyester, polycarbonate, etc) would be “permeable” to *all* of the known gases or which films would exhibit the desired selectivity that would prevent the transport of *any* reaction product out of the cell. This information is not currently available.

(4) The level of one of ordinary skill:

The level of skill would be high, most likely at the Ph.D. level. Such persons of ordinary skill in this art, given its unpredictability, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed.

(6-7) The amount of direction provided by the inventor and the existence of working examples:

The instant specification does not give enough guidance as to how one of ordinary skill in the art could produce the claimed invention using **any** substrate with **any** permeable film covering to produce and test **any** product. Applicant has not provided a generic strategy for determining the chemical and physical composition of the permeable film covering that will allow **any** gas to permeate while preventing the transport of **any** product. Furthermore, applicant has provided only one example using a polycarbonate substrate and polycarbonate film.

(8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure:

The instant claims are drawn to an apparatus described as a “reactor plate” with a comprising a “substrate” and a “permeable film covering.” However, the instant specification does not provide to one skilled in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed in making and using the full scope of the claimed method. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention **as broadly as it is claimed**. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 & n.23 (Fed. Cir. 1991). Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed. Thus, due to the inadequacies of the instant disclosure, one of ordinary skill would not have a reasonable expectation of success and the practice of the full scope of the invention would require undue experimentation.

Response to Arguments

6. Applicant's arguments in Paper No. 9 have been fully considered but they are not found persuasive. The examiner's rationale is set forth below.
7. Applicants argue that the amended claims are enabled. Specifically, applicant states, "The Office Action states that "the specification, while being enabling for ... polycarbonate substrate and a permeable polycarbonate film covering used for the catalytic production of aromatic carbonates ... does no reasonably provide enablement for any apparatus... and any permeable film covering used for any chemical reaction. Claim 1 has been amended to a reactor plate "for the catalytic production of aromatic carbonates," "a preamble polycarbonate film covering" and a "polycarbonate substrate." Claims 2 to 11, 13 and 16 depend from claim 1. The amendment should overcome the rejections of claims 1 to 11 and 13 to 16 under U.S.C. §112, first paragraph" (see Paper No. 9, page 3, paragraph 5). However, applicant does not explain how said amendments overcome the prior rejections, applicant only states that said amendments "should" overcome the 35 U.S.C. §112, first paragraph rejections without any additional explanation.
8. The examiner's position is that applicants' amendments do not overcome the rejections of claims 1 to 11 and 13 to 16 under U.S.C. §112, first paragraph. The issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. See the decisions in *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA

1970), *Amgen v. Chugai Pharmaceuticals Co. Ltd.*, 13 USPQ2d, 1737 (1990), and *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988). *In re Wands* stated that the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. All of these factors were addressed in the initial rejection.

9. The examiner maintains for the instant case that the art is unpredictable and that the instant disclosure is not enabling for the full scope of the claims. The following portion of the rejection is particularly relevant (see Paper No. 6, page 6):

Furthermore, one of ordinary skill in the art could not predict which films (e.g., polyester, polycarbonate, etc) would be “permeable” to *all* of the known gases or which films would exhibit the desired selectivity that would prevent the transport of *any* reaction product out of the cell. This information is not currently available.

10. The newly amended claims do not overcome this rejection because the claims are still drawn to a permeable film (albeit now limited to a polycarbonate film) that can selectively admit “*any*” reactant and prohibit the transport of “*any*” product, which still represents broad scope of an unpredictable nature. This rejection was not made over claim 12 because the reactants and products are clearly specified in claim 12 i.e., “admits transport of oxygen and carbon monoxide and prohibits transport of a diaryl carbonate.” Applicants’ further amendment in the preamble (i.e., a reactor plate “for the catalytic production of aromatic carbonates”) does not cure this problem for the other claims (i.e., pending claims 1-7, 10-11 and 16) because the preamble is not given any patentable weight. A preamble is generally not accorded any patentable weight where

it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

11. Applicant's claimed scope of products and reactants represents only an invitation to experiment regarding possible compounds and their selective permeability. Specifically, the instant specification *fails to identify all of the possible reactants and products that could be selectively admitted or prohibited from transport by the selective permeable polycarbonate film or what properties these reactants and products might share* that would teach one of ordinary skill in the art how to practice the invention as broadly as it is claimed. Furthermore, since applicant did not address this aspect of the rejection in the previous office action i.e., applicant did not address any of the Wands factors set forth in Paper No. 6, the above rejection under the first paragraph of 35 U.S.C. 112 is maintained for the reasons previously stated.

Maintained Claim Rejections - 35 USC § 112, first paragraph

12. Claims 1-7, 10-12 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an apparatus comprising a single substrate composed of one type of material (e.g., polycarbonate), does not reasonably provide enablement for a single substrate composed of more than one type of material (e.g., once cell is composed of polycarbonate, another cell is composed of polyester). The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims (see as an example claim 15 stating, "wherein at least one cell is a cell is formed from a polycarbonate substrate" implying that each cell may be made of a different material).

It is clear from applicant's specification how one might produce the claimed invention only when the solid support and permeable film covering are composed of polycarbonate; however, there is insufficient guidance as to how to carry out the production of any apparatus comprising *any* substrate and *any* permeable film covering. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

- (1) the breadth of the claims;
- (2) the nature of the invention;
- (3) the state of the prior art;
- (4) the level of one of ordinary skill;
- (5) the level of predictability in the art;
- (6) the amount of direction provided by the inventor;
- (7) the existence of working examples; and
- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1-2) The breadth of the claims and the nature of the invention:

For **claims 1-16**, applicant has disclosed an apparatus that is very broad in scope.

The "substrate" as disclosed by the applicant can be composed of more than one material e.g., cell 1 is polycarbonate, cell 2 is polyester, cell 3 is polypropylene.

(3 and 5) The state of the prior art and the level of predictability in the art:

There are no examples of a single microtiter plate wherein each well of the plate is made from a different material. Furthermore, the examiner is not aware of any other “substrate” disclosing this amalgamation of materials.

Since there is no examples the level of predictability in the art would be low or absent.

(4) The level of one of ordinary skill:

The level of skill would be high, most likely at the Ph.D. level. Such persons of ordinary skill in this art, given its unpredictability, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed.

(6-7) The amount of direction provided by the inventor and the existence of working examples:

The instant specification does not give enough guidance as to how one of ordinary skill in the art could produce the claimed invention using a substrate with multiple cells wherein each cell is composed of **any** substance. Applicant has not provided a generic strategy for making such a substrate. Furthermore, applicant has not provided any examples; applicant’s only example does not teach the idea that a variety of materials may be used to make each cell for a particular substrate. Applicant’s example shows that all of the cells are made of polycarbonate.

(8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure:

The instant claims are drawn to an apparatus described as a “reactor plate” with a comprising a “substrate” and a “permeable film covering” wherein the “substrate with an

array of reaction cells" can possess "reaction cell" made from different materials for the single substrate (e.g., well #1 is polycarbonate, well #2 is polyester, etc.). However, the instant specification does not provide to one skilled in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed in making and using the full scope of the claimed method. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention *as broadly as it is claimed*. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 & n.23 (Fed. Cir. 1991). Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed. Thus, due to the inadequacies of the instant disclosure, one of ordinary skill would not have a reasonable expectation of success and the practice of the full scope of the invention would require undue experimentation.

Response to Arguments

13. Applicant's arguments in Paper No. 9 have been fully considered but they are not found persuasive. The examiner's rationale is set forth below.

14. Applicants argue that the amended claims are enabled. Specifically, applicant states, "The Office Action states that the specification is enabling for a one material, single substrate apparatus but not for a single substrate "composed of more than one type of material." Again, claim 1 has been amended to a "polycarbonate substrate." Claims 2 to 11, 13 and 16 depend

from claim 1. The amendment should overcome the rejection of claims 1 to 16 under U.S.C. §112, first paragraph" (see Paper No. 9, page 3, paragraph 6). However, applicant does not explain how said amendments overcome the prior rejections, applicant only states that said amendments "should" overcome the 35 U.S.C. §112, first paragraph rejections without any additional explanation.

15. The examiner's position is that applicants' amendments do not overcome the rejections of claims 1 to 16 under U.S.C. §112, first paragraph. The issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. See the decisions in *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), *Amgen v. Chugai Pharmaceuticals Co. Ltd.*, 13 USPQ2d, 1737 (1990), and *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988). *In re Wands* stated that the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. All of these factors were addressed in the initial rejection.

16. The examiner maintains for the instant case that the art is unpredictable and that the instant disclosure is not enabling for the full scope of the claims. The following portion of the rejection is particularly relevant (see Paper No. 6, page 9):

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For claims 1-16, applicant has disclosed an apparatus that is very broad in scope. The “substrate” as disclosed by the applicant can be composed of more than one material e.g., cell 1 is polycarbonate, cell 2 is polyester, cell 3 is polypropylene ... There are no examples of a single microtiter plate wherein each well of the plate is made from a different material. Furthermore, the examiner is not aware of any other “substrate” disclosing this amalgamation of materials. Since there is no examples the level of predictability in the art would be low or absent.

17. The newly amended claims do not overcome this rejection because the amendment does NOT narrow the broad claims or alleviate their unpredictable nature. The statement in amended claim 1, “wherein the at least one cell is a cell that is formed from a polycarbonate substrate with two opposing walls” still permits the possibility that “another” cell may be composed of a different material. Consequently, the previous arguments in their entirety still apply i.e., the amendment simply does not address the issue. Furthermore, since applicant did not address this aspect of the rejection in the previous office action i.e., applicant did not address any of the Wands factors set forth in Paper No. 6, the above rejection under the first paragraph of 35 U.S.C. 112 is maintained for the reasons previously stated.

Maintained Claim Rejections - 35 USC § 112, second paragraph

18. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. Claims 1-7, 10-12 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- A. The term “reactor plate” in claim 1 is not defined by the claim or the specification and is an indefinite and/or unclear term. For example, how does the term “reactor” in the phrase “reactor plate” limit the scope of the invention? Does the plate itself “react” as a catalyst? Does the plate itself change physically or chemically during the course of the reaction? Furthermore, how does the word “plate” limit the scope of the invention? For example, does the word “plate” encompass only a “flat metallic” surface or could it also include a “concave glass” surface? Consequently, it is not possible to determine the metes and bounds of the invention as claimed. Therefore, claim 1 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.
- B. The term “substrate” in claim 1 is not defined by the claim or the specification and is indefinite and/or unclear. For example, a “substrate” could refer to any compound that participates in an enzymatic reaction, a polymeric resin such as a bead or other type of solid-support, or a soluble dendrimer used in cascade synthesis. Consequently, it is not possible to determine the metes and bounds of the invention as claimed. Therefore, claim 1 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.
- C. The term “reaction cells” in claim 1 is not defined by the claim or the specification and is indefinite and/or unclear. For example, does the term “reaction cells” refer to the wells of a microtiter plate or to living biological cells? Consequently, it is not possible to determine the metes and bounds of the

invention as claimed. Therefore, claim 1 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

D. The phrase “substrate with an array of reaction cells” in claim 1 is indefinite and/or unclear. In this context, does the word “with” mean that an array of reaction cells “accompanies” the substrate (i.e., the substrate and the array of reaction cells are two separate items) or does the word “with” show that the “array of reaction cells” is qualifying property that further limits the word substrate (i.e., the substrate and the array of reaction cells are the same item)? Consequently, it is not possible to determine the metes and bounds of the invention as claimed. Therefore, claim 1 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

E. Claim 1 recites the limitation "the cell" in line 5 (claim 1, line 4 refers to “the one cell”). There is insufficient antecedent basis for this limitation in the claim. The examiner recommends changing the phrase to “the one cell.” Therefore, claim 1 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

F. Claims 2-12 recite the limitation "the film" (whereas claim 1 refers to “the permeable film”). There is insufficient antecedent basis for this limitation in the claim. The examiner recommends changing the phrase to “the permeable film.” Therefore, claims 2-12 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

G. The terms "about", "preferably about" and “desirably about” in claims 2-7 are relative terms which render the claims indefinite. The terms are not defined by

the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not possible to ascertain how much more or less cc(STP)-mm/cm²-sec-cmHg constitutes “about 5 X 10⁻¹⁰,” or “preferably about 2 X 10⁻⁸” or “desirably about .01.” Therefore, claims 2-7 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

H. The term “shallow cell” in claim 13 is a relative term, which renders the claims indefinite. The term “shallow” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore, claims 13 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

I. The term “permeable film” in claim 1 is a relative term, which renders the claims indefinite. The term “permeable” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore, claims 1 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

J. The phrase “wherein the at least one cell is a cell is formed from a polycarbonate substrate” is indefinite and/or unclear. Does the applicant mean that the cells are made of the same polycarbonate material as the permeable film? Does the applicant mean that a “substrate with an array of reaction cells” can be composed

of more than one material e.g., one cell is made of polycarbonate while another cell is made of say polyester? Consequently, it is not possible to determine the metes and bounds of the invention as claimed. Therefore, claim 15 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

Response to Arguments

20. Applicant's arguments filed November 29, 2001 have been fully considered but they are not found persuasive. The examiner's rationale is set forth below.

21. For sections A-D, applicant argues that "The Office Action states that "reactor plate" (paragraph A), "substrate" (paragraph B), "reaction cells" (paragraph C) and "substrate with an array of reaction cells" (paragraph D) are not defined in the specification and are indefinite. However, the terms "reactor plate," "substrate", "reaction cells" and "substrate with an array of reaction cells" are defined in the specification ... Additionally, the terms "reactor plate," "substrate," "reaction cells" and "substrate with an array of reaction cells" are well-known terms in the combinatorial art" (see Paper No. 9, page 4, paragraph 1).

The Examiner's position is that the specification as indicated by applicant does not define said terms, but merely provides examples in which the terms are used. Furthermore, the Examiner contends that these terms are not "well known" in the art and that merely providing an example of a patent wherein the terms are used does not make those terms well known. Furthermore, even assuming *arguendo* that said terms are defined and/or well known in the art, applicant has not addressed the ambiguities that were set forth in the previous office action.

Applicant did not explain how the specification or literature remedies the stated ambiguities (see Paper No. 6, paragraph 13, sections A-D). Consequently, the previous rejections under 35 U.S.C. 112, second paragraph for sections A-D are maintained for the reasons of record.

22. For sections E-F, the rejections are withdrawn.

23. For section G, applicant argues, “One skilled in the chemical art would understand what is claimed in claims 2 to 7 in view of the specification. See Seattle Box C., v. Industrial Crating & Packing, Inc., 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984) and MPEP 2173.05(b). Relative terminology and in particular the use of the term “about” does not render a claim indefinite. See Ex parte Eastwood, 163 USPQ 316 (Bd. App. 1968) and W.L. Gore & Associated, Inc. v. Garlock, inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). This basis of rejection should be withdrawn” (see Paper No. 9, page 4, paragraph 3)

The Examiner’s position is that the terms “about”, “preferably about” and “desirably about” in claims 2-7 are relative terms, which render the claims indefinite. The Examiner is unaware of any *per se* rule that renders the terms “about”, “preferably about” and “desirably about” acceptable under all circumstances. As stated in the previous office action, one skilled in the chemical art would not be reasonably apprised of the scope of the invention because it is not possible to ascertain how much more or less cc(STP-mm/cm²-sec-cmHg constitutes “about 5 X 10⁻¹⁰” or “preferably about 2 X 10⁻⁸” or “desirably about 0.01.” For example, what are the metes and bounds of “desirably about .01”? Would .02 fall within this range? How about .1? What if

the “desirability” changes over time, does the patent protection also change? Consequently, the previous rejection under 35 U.S.C. 112, second paragraph is maintained.

24. For sections **H-I**, the rejections are withdrawn.

25. For section **J**, applicant argues that the term “substrate” is defined by the specification and/or is well known in the art and presumably obviates the indefinite rejection over the entire phrase i.e., “wherein the at least one cell is a cell is formed from a polycarbonate substrate” (see Paper No. 9, page 4, paragraph 1) (Please note applicant also addresses this point in response to the 35 U.S.C. §112, first paragraph rejection in Paper No. 9, page 3, paragraph 6). However, the Examiner’s position is that the phrase “wherein the at least one cell is a cell is formed from a polycarbonate substrate” is still indefinite for the reasons of record i.e., defining the word “substrate” would not render this entire phrase clear because it is still not clear whether applicant means that a “substrate with an array of reaction cells” can be composed of more than one material e.g., one cell is made of polycarbonate while another cell is made of say polyester? (see Paper No. 6, paragraph 13, section J) and that by incorporating this indefinite statement in claim 1 only serves to render claim 1 and all dependent claims indefinite. Consequently, the Examiner maintains the rejection over the newly amended claim 1 for reasons of record.

Status of Claims/Conclusion

26. No claims are allowed.

27. Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D. Epperson, Ph.D. whose telephone number is (703) 308-2423. The examiner can normally be reached on Monday-Thursday from 9:30 to 7:00 and alternate Fridays.

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of

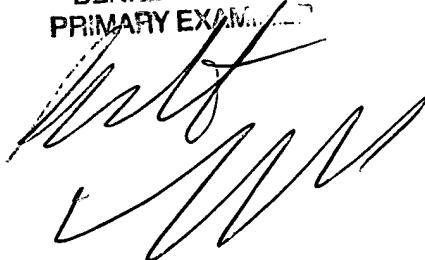
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a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Jon D. Epperson, Ph.D.

December 6, 2002

BENNETT CELSON
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "BENNETT CELSON", is written over the typed name. It consists of a series of fluid, overlapping lines.